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HAI-Europe Statement on the Draft Global Strategy and Plan of Action, IGWG 2bis. April 2008

Health Action International (HAI) Europe repeats their support to the ongoing WHO initiative to develop a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

We wish to make the following comments on the proposed text:

Summary

- As mentioned in CIPIH; the right to health should take precedence over commercial interests. (principles, 18)
- The scope of diseases should not be limited to type II and III diseases but should also include type I diseases. Type I diseases like diabetes and cancer are becoming an increasing problem for developing countries and it would be very ineffective for the strategy and plan of action to exclude them. (principles, 15, footnote / Element 1, 27)
- Proposals allowing the de-linkage of the cost of R&D and the price of medicines should be assessed and explored
- The progressive concepts of open source compound libraries and digital databases, patent pools and alternative licensing policies should be further developed and implemented. (2.3) (2.4d)
- ‘‘Research’’ for health products for the developing countries should attain to encompass discovery, development and delivery.
- Competition and the use of TRIPS flexibilities should be promoted. The use of TRIPS-plus provisions in trade agreements should be rejected.
- Research in traditional medicines should be encouraged, taking into account the rights of local communities and international efforts to protect traditional knowledge. (1.3)

Scope of diseases (Principles)

As in the summary; the scope of diseases should not be limited to type II and III diseases but should also include type I diseases. Type I diseases like diabetes and cancer are becoming an increasing problem for developing countries and it would be very ineffective for the strategy and plan of action to exclude them.

The CIPIH report, the recommendations on which the IGWG is intended to build, deals with type I, II and III diseases. This clarification is helpful because it offers an analysis of the economic causes of access and R&D problems and provides a frame for designing solutions. The types of diseases are never meant to indicate hierarchy (Principles, 15, footnote / Element 1, 27).

Promoting R&D (Elements 2&5)

HAI Europe welcomes the idea of exploring new mechanisms for financing R&D, but we are convinced that for it to succeed we need stronger commitment. Proposals exploring the de-linking of R&D costs and the price of medicine must be actively supported, pursued and developed.

It is clear that the current patent-driven R&D system fails to provide incentives to stimulate the necessary R&D into medicines for diseases that disproportionately affect developing countries. Indeed the CIPIH¹ report concluded that patents do not work as incentives for research and development targeting diseases of poor people. There is growing recognition of the need for alternative approaches.

These should be characterized by the principle: innovation plus access. *Real* innovation can only be translated into *real* benefit if access to innovation is assured. One important limitation to access are prices, and high prices are often related to production monopolies and exclusive market rights.

If we are to de link the costs of R&D and prices of medicine, exploration has to take place into models that promote prize funds, patent pools or other mechanisms that have a pro-health approach to priority setting and financing.

Prize Fund: Stronger attention needs to be paid to prize funds as these reward successful therapeutic innovation with adequate financial payments instead of granting patent-monopolies.

Non-profit R&D models: These models have proven to be successful yet these depend on depend on financial commitments by governments and other donors and on political will. HAI firmly supports these initiatives.

Publicly funded R&D: It is estimated that globally up to 50% of new R&D resources come from general taxes revenues. We have to make the results of publicly funded R&D accessible to initiatives targeting developing countries. This could be achieved through alternative licensing or through placing these in the public domain.

Advanced market commitments; it is still not clear what the effect of these are, also in relation to other models. It would be important to conduct more research into the effectiveness and efficiency of AMCs before these models are endorsed. As AMCs are based on exclusive market rights, they might not provide an incentive for industry to share knowledge and technology.

¹ www.who.int/intellectualproperty/report/en/index.html

Patent pools: Offer a potential solution to barriers in product development. For example for the development of generic fixed-dose combinations (FDC) of the new WHO recommended first line-regimen for HIV/AIDS, three different patent holders are involved².

Intellectual property Public Health and Access: Elements 3,5&6

It is essential to keep a strong position on **TRIPS flexibilities** in the Global Strategy and Plan of Action. The strategy should unambiguously support the use of the TRIPS flexibilities as recalled by the Doha Declaration on the TRIPS Agreement and Public Health. Hence, we should see clear-cut language in Element 5 that calls for the use of these provisions to increase access, produce and export generics and to overcome patent barriers in research.

The “right to health takes precedence over commercial interests” - is wording used in TRIPS agreement. It’s essential to avoid **TRIPS plus**. Don’t go back on what already had been achieved in other fora!

The US and the European Commission are pressing for TRIPS-plus provisions in some of their Bilateral Trade Agreements. For example, through the inclusion of data exclusivity provisions in their bilateral and regional trade agreements. This undermines the spirit and aims of the Doha Declaration and is unacceptable from a public health perspective. The IGWG should be a balance to this.

The document also calls for the exchange of information between national regulatory authorities (**NRA**) and patent offices in developing countries to be established or strengthened. It is important that this does not result in the NRA playing an active role in patent enforcement, as is foreseen in some trade agreements. NRAs should fulfil their function of providing a health perspective to patent examiners.

² MSF, 2008, IGWG.

Specific suggestions

Principles:

p.5 - 15, footnote: Delete last part “**For the purpose of the Strategy, the focus.....as appropriate.**” (*Strategy should include Type I diseases*)

p.6- 18, Keep: “**The right to health takes precedence over commercial interests**”

Element 2

p.9- 30, (2.2) a) Delete ‘**and appropriate**’ ‘**voluntary**’ . *These two words make the action point weaker. It is an important and promising action point which should be as strong as possible.*

p.11 30 (2.4d) Important to keep. *See above*

e) Important to keep. Yet delete ‘**of developing countries**’ . *Research exemption is already in many developed countries’ legislation. It should be promoted for every country.*

Element 3

32 (3.2) c) Keep text in brackets.

p.12 32 (3.4) See above, a lot of expertise in other fora, maybe leave to WIPO.

p.13 32 (3.5) Delete **alternative**, (in brackets) add **access**; “**developing and implementing incentives for innovation and access**”

Element 4

34 (4.1) b) Delete in brackets; *essential technology does not exist; one needs a different technology for every medicine.*

p.14 34 (4.2) b) Delete . “*Natural products*” *is a new term in this context, not clearly defined. If this is referring to traditional medicine, then delete.*

(4.3) Delete ‘**voluntary**’ in both a) and b) . *This makes the points very weak. We need strong promoting of alternative mechanisms as it has become clear (as repeatedly mentioned in CIPIH report) that current mechanisms are not appropriate for all the worlds health needs.*

c) Preference for ‘**alternative**’ over ‘**complementary**’.

Element 5

p.15 36 (5.1) a) Strong preference for keeping second option; ‘**Encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation, especially to meet the R&D needs of the developing countries.**’ *This text is more in favour of health than the 1st option.*

c) Keep

e) Keep. *WHO must play leading role here.*

p.17 36 (5.2) b) Keep subparagraph! option 1 or 2. Option 1: Delete ‘**promote**’ and ‘**not**’ and ‘**affordable**’. Keep: ‘**WHO and WTO**’ ‘**discourage** : ‘**WHO and WTO to discourage bilateral trade agreements that incorporate “TRIPS-plus” protection in ways that might reduce access to medicines in developing countries.**’ *See general statement*

c) *Important that as much as possible is kept in.*

p.18 (5.3) a) Strong preference 1st option.; Delete : **complementary**, and/or **additional**, and that are consistent with domestic regimes for protecting intellectual property and rights

b) Delete: ‘**Expand/consider the use of**’ > Use: ‘**Explore**’. *AMCs are a new model with unknown efficacy therefore they need to be EXPLORED, not EXPANDED!!*

c) Take first option. *The detrimental impact of data exclusivity for access to medicine has already been emphasized in CIPIH report; developing countries should not impose restrictions.*

Element 6

p.21 (6.3) a) Delete '**patent expiry**'. c) Delete: '**review**'/ Keep: '**remove**'. *Tariffs and taxes have proven to have a major negative impact on access to medicine.*